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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,213	10/20/1999	TIMOTHY J. O'BRIEN	D6064CIP	3804

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/421,213

Applicant(s)

O'BRIEN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 25-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2002 has been entered.

2. Claims 1-52 are pending.

Claims 1-21 and 25-52, drawn to non-elected inventions are withdrawn from examination.

Claims 22 and 24 have been amended.

Claims 22-24 are examined on the merits.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the U.S. serial application 09/027,337, now U.S. patent 5,972,616, filed February 20, 1998 upon which priority is claimed fails to provide adequate support for claims 22-24 of this application. There is no evidence found within the specification of the said patent that Applicants had contemplated the production of antibodies specific

for TADG-15 protein comprising amino acids 1 to 615 of SEQ ID NO: 2. Accordingly, priority of the instant application is the effective filing date of the application, October 20, 1999.

Drawings

4. The drawings were objected to because of reasons cited on form PTO 948 completed by draftsman mailed with the first action on the merits, June 29, 2000. Correction is required.

NEW INFORMATION ON HOW TO EFFECT DRAWING CHANGES

5. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

6. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

7. Claims 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants' have amended both claims, 22 and 24 to include the recitation "wherein said antibody is directed against all or part of amino acids 1 to 614 of SEQ ID NO: 2". Claim 24 has additionally been amended to recite "amino acids 1 to 615". SEQ ID NO: 2, termed TADG-15 consists of 855 amino acids. Applicants have pointed out in the amendment filed January 14, 2002 where support for this language can be found in the specification. They suggest that the legend to Figure 4 of the instant specification on page 10, lines 16-20 indicate that amino acid residues 615-855 are considered to represent a distinct domain from the rest of the distinct domains. While the schematic is representative of the TADG-15 domains and the legend sets forth these specific domains, there is no evidence within the specification that sustain Applicants' amendments to the claims. There is no support in the disclosure that suggests that Applicants contemplated antibodies to specific regions, i.e. amino acids 1 to 614 of SEQ ID NO: 2 at the time the claimed invention was made. Applicants are required to cancel

the new matter in reply to this Office action if proper support for the amendments is not provided.

If Applicants reintroduce originally presented claims (claims prior to January 14, 2002 amendment) to obviate the instant new matter rejection accordingly the U.S.C. 103(a) rejection set forth in paragraph 11, page 5 of the first action on the merits mailed June 29, 2000 as Paper number 10 will be reinstated.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claim 24 is rejected under 35 U.S.C. 102(a) as being anticipated by Lin et al. (The Journal of Biological Chemistry 274(26): 18231-18236, June 25, 1999). Lin discloses anti-matriptase antibodies, monoclonal antibody (mAb) 21-9 and mAb M32 that are directed against the sequence in Figure 3 found on page 18233 (see page 18232, Figures 1 and 2, second column, Immunoblot analysis section and bridging paragraph on page 18233). The sequence of Figure 3 corresponds to amino acid residues 173-855 of SEQ ID NO:2 of the instant invention (see the attached database sheet). Thus the reference is disclosing mAbs, which bind to a portion of SEQ ID NO: 2. Applicants' claim is directed to an antibody, which binds a portion of amino acids 1-

614 of SEQ ID NO: 2. Because of the overlap between the reference (mAbs binds to amino acid residues 173-855 of SEQ ID NO:2) and the reference (amino acids 1-614 of SEQ ID NO: 2), the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (The Journal of Biological Chemistry 274(26): 18231-18236, June 25, 1999). As stated above Lin teaches antibodies directed against part of amino acids 1 to 614 of SEQ ID NO:2. This reference also teaches a means of detecting the said antibodies utilizing a peroxidase-labeled secondary antiserum (see page 18232, Figures 1 and 2 and second column, Immunoblot analysis). The Lin reference does not teach a kit comprising the said antibodies and a means of detection.

Although the prior art does not teach antibodies contained within a kit, however it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to package the reagents taught by Lin into a convenient kit form for the purposes of increased marketability convenience, reliability and economy.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alana M. Harris, Ph.D.
March 21, 2002